

**WHAT IS CLAIMED IS:**

1. A tissue biopsy device for accessing and collecting a tissue specimen from a target site within a patient, comprising:

- a. an elongated probe member which has a longitudinal axis, which has a proximal end configured to be secured to a drive, which has an inner lumen extending therein, which has a penetrating distal tip and which has an aperture proximal to the penetrating distal tip configured to receive tissue from the target site; and
- b. an elongated tissue cutting member which is disposed within the elongated probe member, which has at least one tissue cutting edge with a longitudinal orientation at an angle with respect to the longitudinal axis less than  $90^\circ$  over a length thereof, which has an inner lumen extending therein, which is configured to be operably connected to at least one drive unit to move the tissue cutting member to cut a tissue specimen from tissue extending into the tissue receiving aperture of the elongated member.

2. The biopsy device of claim 1 wherein the probe member includes a rotatable tissue accessing cannula which is slidably disposed concentrically about the tissue cutting member, has a proximal end, has a distal end seated against a proximal surface of the tissue penetrating distal tip, has an inner lumen extending therein, has a tissue receiving side port spaced proximal to the distal end thereof in fluid communication with the inner lumen and disposed in the open section of the outer cannula and is operably secured to a drive unit in the housing to rotate the tissue accessing cannula to adjust the operating location of the tissue receiving side port.

3. The biopsy device of claim 2, wherein the cutting edge of the tissue cutting member is defined at least in part by an arcuate wall section of the tissue cutting member.

4. The biopsy device of claim 3 wherein the arcuate wall section of the tissue cutting member has a longer arc length than the arc length of the aperture.

5. The biopsy device of claim 4 wherein aperture extends through an arc of less than 90°.

6. The biopsy device of claim 2, wherein the cutting edge of the tissue cutting member is longer than the aperture of the tissue accessing cannula.

7. The biopsy device of claim 1 wherein the inner lumen defined at least in part by the tissue cutting member is configured to access a vacuum source to transport a tissue specimen through the inner lumen thereof to a tissue collector in fluid communication with the inner lumen.

8. The biopsy device of claim 2, wherein the tissue cutting member is configured for rotational movement about a longitudinal axis.

9. The biopsy device of claim 8, wherein the tissue cutting member is also configured for reciprocating longitudinal movement.

10. The biopsy device of claim 9, wherein the tissue cutting member is configured for reciprocating longitudinal movement of between about 0.01 inch and about 0.2 inch (0.25-5.1 mm).

11. The biopsy device of claim 3, wherein the arcuate wall section of the tissue cutting member has longitudinally oriented cutting edges.

12. The biopsy device of claim 11 wherein the longitudinally oriented cutting edges of the tissue cutting member has a leading distal cutting edge portion and a trailing proximal cutting edge portion.

13. The biopsy device of claim 11 wherein the tissue cutting member has a non-cutting edge which extends parallel with the cutting edge.

14. The biopsy device of claim 13 wherein the cutting and non-cutting edges of the tissue cutting member define in part a tissue receiving aperture.

15. The biopsy device of claim 2, wherein the tissue cutting member is configured for longitudinal movement along a longitudinal axis.

16. The biopsy device of claim 15, wherein the tissue cutting member is also configured for oscillating rotational movement.

17. The biopsy device of claim 1 wherein the aperture has at least one longitudinally oriented tissue cutting edge which engages a tissue cutting edge of the tissue cutting member.

18. The biopsy device of claim 17 wherein the tissue cutting edge of the tissue cutting member has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 20° to about 80°.

19. The biopsy device of claim 17 wherein the tissue cutting edge of the tissue cutting member has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 30° to about 75°.

20. The biopsy device of claim 17 wherein the tissue cutting member has a beveled needle like distal tip.

21. The biopsy device of claim 17 wherein the aperture has a tissue cutting distal edge.

22. A tissue biopsy device for accessing and collecting a tissue specimen from a target site within a patient, comprising:

- a. a drive housing which has a plurality of drive units;
- b. an outer member which is releasably secured to the drive housing, which has a proximal tubular portion, which has an inner lumen extending within the proximal tubular portion, which has a tissue penetrating distal tip, which has an open section proximal to the tissue penetrating distal tip and which has a supporting strut extending from the penetrating distal tip to the proximal tubular portion;
- c. a tissue accessing cannula which is slidably disposed at least in part within the inner lumen of the proximal tubular portion of the outer member, which has an inner lumen extending therein, and which has a tissue receiving aperture spaced proximal to the distal end thereof in fluid communication with the inner lumen of the accessing cannula and which is operably secured to a drive unit in the drive housing to rotate the tissue receiving cannula to adjust the orientation of the tissue receiving aperture; and
- d. an elongated tissue cutting member which is formed at least in part of a tubular member, which is slidably disposed within the inner lumen of the tissue accessing cannula, which has a tissue cutting edge, which has an inner lumen extending therein configured to receive a tissue specimen cut by the tissue cutting member, and

which is connected to a drive unit to move the tissue cutting member within the inner lumen of the tissue accessing cannula.

23. The biopsy device of claim 22, wherein the cutting edge is parallel to a longitudinal axis of the tissue cutting member.

24. The biopsy device of claim 22, wherein the cutting edge of the tissue cutting member is defined at least in part by a arcuate wall section thereof.

25. The biopsy device of claim 22 wherein the arcuate wall section of the tissue cutting member has a longer arc length than the arc length of the tissue receiving aperture of the tissue accessing cannula.

26. The biopsy device of claim 22, wherein the cutting edge of the tissue cutting member is longer than the aperture of the tissue accessing cannula.

27. The biopsy device of claim 22 wherein the tissue accessing cannula has a distal end seated against a proximal surface of the tissue penetrating distal tip of the outer member.

28. The biopsy device of claim 22 wherein the tissue accessing cannula has a distal end seated in a circular groove in a proximal surface of the tissue penetrating distal tip of the outer member.

29. The biopsy device of claim 22 wherein the inner lumen of the tissue cutting member is configured to access a vacuum source to transport a cut tissue specimen through the inner lumen thereof to a tissue collector in fluid communication with the inner lumen of the tissue cutting member.

30. The biopsy device of claim 22 wherein the arcuate wall section of the tissue cutting member has an arc length greater than a width of the aperture in the outer member.

31. The biopsy device of claim 22, wherein the tissue cutting member is configured for longitudinal movement along a longitudinal axis.

32. The biopsy device of claim 22, wherein the tissue cutting member is configured for reciprocal longitudinal movement.

33. The biopsy device of claim 22, wherein the tissue cutting member is configured for reciprocal longitudinal movement of between about 0.01 inch and about 0.2 inch.

34. The biopsy device of claim 23, wherein the arcuate wall section of the tissue cutting member has longitudinal oriented cutting surface along both edges.

35. The biopsy device of claim 22 wherein the aperture has at least one longitudinally oriented tissue cutting edge which engages a tissue cutting edge of the tissue cutting member.

36. The biopsy device of claim 35 wherein the tissue cutting edge of the tissue cutting member has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 20° to about 80°.

37. The biopsy device of claim 35 wherein the tissue cutting edge of the tissue cutting member has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 30° to about 75°.

38. The biopsy device of claim 35 wherein the tissue cutting member has a beveled needle like distal tip.

39. The biopsy device of claim 22 wherein the aperture has a tissue cutting distal edge.

40. A probe for a tissue biopsy device for accessing and collecting a tissue specimen from a target site within a patient, comprising:

- a. an outer member which has a proximal tubular portion configured to be releasably secured to a drive housing, which has an inner lumen extending therein, which has a tissue penetrating distal tip, which has an open section proximal to the penetrating distal tip and a supporting strut extending from the penetrating distal tip to the proximal tubular portion;
- b. a tissue accessing cannula which is slidably disposed at least in part within the inner lumen of the tubular portion of the outer member, which has an inner lumen extending therein, and which has a tissue receiving aperture spaced proximal to the distal end thereof in fluid communication with the inner lumen of the accessing cannula and which is configured to be operably secured to a drive unit in a drive housing to rotate the tissue receiving cannula to adjust the orientation of the tissue receiving aperture; and
- c. an elongated tissue cutting member which is slidably disposed within the inner lumen of the tissue accessing cannula, which has at least one longitudinal tissue cutting edge, which defines at least in part an inner lumen for receiving tissue cut by the tissue cutting surface, and which is connected to a drive unit to move the tissue cutting member within the inner lumen of the tissue accessing cannula.

41. The probe of claim 40 wherein the tissue cutting member is formed at least in part of a tubular member.

42. The probe of claim 41 wherein the tissue cutting member is rotatably disposed within the inner lumen of the outer member, has a longitudinal axis, has a longitudinal tissue cutting edge oriented at an angle with respect to the longitudinal axis,

has an inner lumen extending therein for receiving tissue cut by the tissue cutting edge and is configured for rotation within the inner lumen of the outer member to cut tissue pulled into the inner lumen of the tissue cutting member.

43. The biopsy device of claim 42 wherein the tissue cutting member has a non-cutting surface which defines a tissue receiving aperture along with the tissue cutting edge.

44. The biopsy device of claim 43 wherein the non-cutting edge of the tissue cutting member is parallel with the cutting edge thereof.

45. The biopsy device of claim 40 wherein the cutting edge of the tissue cutting member has a leading distal cutting edge portion and a trailing proximal cutting edge portion.

46. A method of separating a biopsy tissue specimen from supporting tissue at a target site within a patient's body, comprising:

- a. providing a biopsy device having a biopsy probe comprising:
  - i. an outer member which is releasably secured to a drive housing, which has an inner lumen extending therein, which has a tissue penetrating distal tip secured thereto, which has an open section proximal to the penetrating distal tip and a supporting strut extending from the penetrating distal tip,
  - ii. a tissue accessing cannula which is slidably disposed at least in part within the inner lumen of the outer member, which has an inner lumen extending therein, and which has a tissue receiving aperture spaced proximal to the distal end thereof in fluid communication with the inner lumen of the accessing cannula and which is



operably secured to a drive unit in the drive housing to rotate the tissue receiving cannula to adjust the orientation of the tissue receiving aperture, and

- iii. an elongated tissue cutting member which is formed at least in part of a tubular member, which is slidably disposed within the inner lumen of the tissue accessing cannula, which has at least one tissue cutting edge, which has an inner lumen extending therein for receiving a tissue specimen cut by the tissue cutting edge, and which is connected to a drive unit to move the tissue cutting member within the inner lumen of the tissue accessing cannula;
- b. advancing the probe at least partially into or adjacent to tissue at the target site;
- c. exposing the aperture of the accessing cannula to tissue at the tissue site;
- d. applying a vacuum to the inner lumen of the tissue accessing cannula or the tissue cutting member to draw tissue from the tissue site into the inner lumen of the accessing cannula;
- e. rotating the tissue cutting member to cut tissue extending into the inner lumen from supporting tissue at the tissue site by the cutting edge of the member; and
- f. transporting a tissue specimen through the inner lumen of the tissue cutting member.

47. The method of claim 46 wherein the rotational motion of the tissue cutting member is oscillating motion.

48. The method of claim 46, wherein the tissue cutting member is moved longitudinally in addition to rotating to cut tissue.

49. The method of claim 46, wherein the longitudinal motion of the tissue cutting member is reciprocating motion.

50. The method of claim 46, wherein fluid is provided within the inner lumen of the tissue cutting member distal to a tissue specimen that is higher than the vacuum pressure therein to transport the tissue specimen proximally within the inner lumen of the tissue cutting member.

51. A tissue biopsy device for accessing and collecting a tissue specimen from a target site within a patient, comprising:

- a. an outer tubular member which has an inner lumen extending therein, which has a penetrating distal tip, and which has a tissue receiving aperture proximal to the penetrating distal tip in fluid communication with the inner lumen and having at least one longitudinally oriented, tissue cutting edge; and
- b. an elongated tissue cutting member which is formed at least in part of a tubular member, which is rotatably disposed within the inner lumen of the outer tubular member, which has a longitudinal axis, which has a longitudinal tissue cutting edge oriented at an acute angle with respect to the longitudinal axis, which has an inner lumen extending therein for receiving tissue cut by the tissue cutting edge and which is configured for rotation within the inner lumen of the outer member to cut tissue extending into the inner lumen of the tissue cutting member.

52. A tissue biopsy device for accessing and severing a tissue specimen from supporting tissue at a target site within a patient, comprising:

- a. an elongated probe member which has a longitudinal axis, which has an inner lumen extending therein, which has a tissue penetrating distal tip and which has a tissue receiving aperture proximal to the tissue penetrating distal tip and defined at least in part by one longitudinally oriented, tissue cutting edges; and
- b. an elongated tissue cutting member which is disposed within the inner lumen of the elongated probe member and configured for cutting movements therein, which has a distal portion with a tissue cutting edge radially spaced from and is at least in part oriented at an acute cutting angle with respect to the at least one tissue cutting edge defining in part the aperture of the probe member and which is configured to be connected to at least one drive unit to move the tissue cutting member rotationally and longitudinally to sever from supporting tissue a tissue specimen tissue extending into the open tissue receiving section of the elongated member.

53. The biopsy device of claim 52 wherein the tissue cutting member has an inner lumen extending therein for receiving at least part of a severed tissue specimen.

54. The biopsy device of claim 52 wherein the tissue cutting member has a beveled, needle-like distal tip.

55. The biopsy device of claim 52 wherein the tissue cutting member has a pair of tissue cutting edges.

56. The biopsy device of claim 52 wherein the cutting angle of the cutting edge of the tissue cutting member with respect to the cutting edge of the aperture is about 20° to about 80°.

57. The biopsy device of claim 52 wherein the cutting angle of the cutting edge of the tissue cutting member is about 25° to about 75°.

58. The biopsy device of claim 54 wherein the distal portion of the tissue cutting member is expanded to ensure that the cutting edges thereof engage the edges of the tissue receiving aperture of the probe member.

59. The biopsy device of claim 58 wherein the beveled distal tip of the tissue cutting member has a pair of cutting edges.

60. The biopsy device of claim 59 wherein the beveled distal tip of the tissue cutting member has a longitudinally oriented slot which separates the tissue cutting edges of the tissue cutting member.

61. The biopsy device of claim 60 wherein the longitudinally oriented slot tapers in the proximal direction to smaller transverse dimensions.

62. The biopsy device of claim 60 wherein the distal portion of the tissue cutting member has a transversely oriented slot proximal to the beveled tip.

63. A device for accessing and collecting tissue from a target site within a patient, comprising:

- a. an elongated probe member which has a longitudinal axis, which has a proximal end configured to be secured to a drive, which has an inner lumen extending therein, which has a penetrating distal tip and which has an aperture proximal to the penetrating distal tip configured to receive tissue from the target site; and

- b. an elongated tissue cutting member which is disposed within the elongated probe member, which has at least one tissue cutting edge with a longitudinal orientation at an angle with respect to the longitudinal axis less than 90° over a length thereof, which has an inner lumen extending therein, which is configured to be operably connected to at least one drive unit to move the tissue cutting member to cut a tissue from tissue extending into the tissue receiving aperture of the elongated member.

64. A device for accessing and collecting tissue from a target site within a patient, comprising:

- a. a drive housing which has a plurality of drive units;
- b. an outer member which is releasably secured to the drive housing, which has a proximal tubular portion, which has an inner lumen extending within the proximal tubular portion, which has a tissue penetrating distal tip, which has an open section proximal to the tissue penetrating distal tip and which has a supporting strut extending from the penetrating distal tip to the proximal tubular portion;
- c. a tissue accessing cannula which is slidably disposed at least in part within the inner lumen of the proximal tubular portion of the outer member, which has an inner lumen extending therein, and which has a tissue receiving aperture spaced proximal to the distal end thereof in fluid communication with the inner lumen of the accessing cannula and which is operably secured to a drive unit in

the drive housing to rotate the tissue receiving cannula to adjust the orientation of the tissue receiving aperture; and

- d. an elongated tissue cutting member which is formed at least in part of a tubular member, which is slidably disposed within the inner lumen of the tissue accessing cannula, which has a tissue cutting edge, which has an inner lumen extending therein configured to receive tissue cut by the tissue cutting member, and which is connected to a drive unit to move the tissue cutting member within the inner lumen of the tissue accessing cannula.

65. A probe for accessing and collecting tissue from a target site within a patient, comprising:

- a. an outer member which has a proximal tubular portion configured to be releasably secured to a drive housing, which has an inner lumen extending therein, which has a tissue penetrating distal tip, which has an open section proximal to the penetrating distal tip and a supporting strut extending from the penetrating distal tip to the proximal tubular portion;
- b. a tissue accessing cannula which is slidably disposed at least in part within the inner lumen of the tubular portion of the outer member, which has an inner lumen extending therein, and which has a tissue receiving aperture spaced proximal to the distal end thereof in fluid communication with the inner lumen of the accessing cannula and which is configured to be operably secured to a drive unit in a drive housing to rotate the tissue receiving cannula to adjust the orientation of the tissue receiving aperture; and

c. an elongated tissue cutting member which is slidably disposed within the inner lumen of the tissue accessing cannula, which has at least one longitudinal tissue cutting edge, which defines at least in part an inner lumen for receiving tissue cut by the tissue cutting surface, and which is connected to a drive unit to move the tissue cutting member within the inner lumen of the tissue accessing cannula.

66. A method of separating tissue from supporting tissue at a target site within a patient's body, comprising:

- a. providing a tissue removal device having an elongated probe comprising:
  - i. an outer member which is releasably secured to a drive housing, which has an inner lumen extending therein, which has a tissue penetrating distal tip secured thereto, which has an open section proximal to the penetrating distal tip and a supporting strut extending from the penetrating distal tip,
  - ii. a tissue accessing cannula which is slidably disposed at least in part within the inner lumen of the outer member, which has an inner lumen extending therein, and which has a tissue receiving aperture spaced proximal to the distal end thereof in fluid communication with the inner lumen of the accessing cannula and which is operably secured to a drive unit in the drive housing to rotate the tissue receiving cannula to adjust the orientation of the tissue receiving aperture, and
  - iii. an elongated tissue cutting member which is formed at least in part of a tubular member, which is slidably disposed within the inner

lumen of the tissue accessing cannula, which has at least one tissue cutting edge, which has an inner lumen extending therein for receiving a tissue specimen cut by the tissue cutting edge, and which is connected to a drive unit to move the tissue cutting member within the inner lumen of the tissue accessing cannula;

- b. advancing the probe at least partially into or adjacent to tissue at the target site;
- c. exposing the aperture of the accessing cannula to tissue at the tissue site;
- d. applying a vacuum to the inner lumen of the tissue accessing cannula or the tissue cutting member to draw tissue from the tissue site into the inner lumen of the accessing cannula; and
- e. rotating the tissue cutting member to cut tissue extending into the inner lumen from supporting tissue at the tissue site by the cutting edge of the member.

67. The method of claim 66 wherein severed tissue is transported through the inner lumen of the tissue cutting member.

68. The method of claim 67 wherein the severed tissue is transported by providing a vacuum within the inner lumen of the cutting member.

69. A device for accessing and collecting tissue from a target site within a patient, comprising:

- a. an elongated probe means which has a longitudinal axis, which has a proximal end configured to be secured to a drive, which has an inner lumen extending therein, which has a penetrating means on the distal tip and which has an aperture proximal to the penetrating



means on the distal tip configured to receive tissue from the target site; and

- b. an elongated tissue cutting means which is disposed within the elongated probe member, which has at least one tissue cutting edge with a longitudinal orientation at an angle with respect to the longitudinal axis less than 90° over a length thereof, which has an inner lumen extending therein, which is configured to be operably connected to at least one drive means to move the tissue cutting means to cut tissue from tissue extending into the tissue receiving aperture of the elongated probe means.

70. A method of separating tissue from supporting tissue at a target site within a patient's body, comprising the steps of:

- a. providing a tissue removal means having an elongated probe comprising:
  - i. an outer member which is releasably secured to a drive housing, which has an inner lumen extending therein, which has a tissue penetrating distal tip secured thereto, which has an open section proximal to the penetrating distal tip and a supporting strut extending from the penetrating distal tip,
  - ii. a tissue accessing cannula which is slidably disposed at least in part within the inner lumen of the outer member, which has an inner lumen extending therein, and which has a tissue receiving aperture spaced proximal to the distal end thereof in fluid communication with the inner lumen of the accessing cannula and which is operably secured to a drive unit in the drive housing to rotate the

tissue receiving cannula to adjust the orientation of the tissue receiving aperture, and

- iii. an elongated tissue cutting means which is formed at least in part of a tubular member, which is slidably disposed within the inner lumen of the tissue accessing cannula, which has at least one tissue cutting edge, which has an inner lumen extending therein for receiving a tissue specimen cut by the tissue cutting edge, and which is connected to a drive unit to move the tissue cutting member within the inner lumen of the tissue accessing cannula;
- b. the step of advancing the probe at least partially into or adjacent to tissue at the target site;
- c. the step of exposing the aperture of the accessing cannula to tissue at the tissue site;
- d. the step of applying a vacuum to the inner lumen of the tissue accessing cannula or the tissue cutting member to draw tissue from the tissue site into the inner lumen of the accessing cannula; and
- e. the step of rotating the tissue cutting member to cut tissue extending into the inner lumen from supporting tissue at the tissue site by the cutting edge of the member.